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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,358	10/02/2003	Karine Vidal	88265-6852	8288

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CHICAGO, IL 60690

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/676,358

Applicant(s)

VIDAL ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 and 18 is/are allowed.
- 6) ☒ Claim(s) 1 and 19 is/are rejected.
- 7) ☒ Claim(s) 3-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on January 8, 2007 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1 and 3-19 are pending.

Applicants' amendment filed January 8, 2007 is acknowledged. Applicant's response has been fully considered. Claims 1, 18 and 19 have been amended. Claims 12-16 are non-elected inventions and withdrawn from consideration. Therefore, claims 1, 3-11, and 17-19 are examined.

Withdrawn Objection to the Specification

3. The previous objection to the specification, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 5 in the amendment filed January 8, 2007.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 1, 3-11 and 19 under 35 U. S. C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 5 in the amendment filed January 8, 2007.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Simonet *et al.* (Cell 89, 309-319 (1997)).

Simonet *et al.* teach osteoprotegerin (OPG) is a secreted glycoprotein that regulates bone resorption and has 4 potential sites of N-linked glycosylation (page 310, left column; Fig 1B), OPG is recombinantly synthesized as an approximately 55 kDa monomer within the cell and is converted to disulfide-linked dimer of approximately 110 kDa (the paragraph bridged pages 310 and 311; page 317, right column; claims 1 and 19), which is approximately 130 kDa since the specification does not specifically define the term “approximately”. Although the claim recites osteoprotegerin is obtained from human or bovine milk or colostrum, the claimed osteoprotegerin is not different from the osteoprotegerin made recombinantly as shown in the reference. MPEP 2113 states that “Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself, the patentability of a product does not depend on its method of production.”

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6. Claims 1 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Yano *et al.* (U.S. Patent 6,693,175, effective filing date, July 31, 1998).

Yano *et al.* teach the purification of a monomer (60 kDa) and a dimer (120 kDa) of osteoclastogenesis inhibitory factor (OCIF, another name for osteoprotegerin) made recombinantly (Example 1). Since the specification does not specifically define the term “approximately”, an OCIF with a molecular weight of 120 kDa meets the criteria of claims 1 and 19. Although the claim recites osteoprotegerin is obtained from human or bovine milk or colostrum, the claimed osteoprotegerin is not different from the osteoprotegerin made recombinantly as shown in the reference. MPEP 2113 states that “Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself, the patentability of a product does not depend on its method of production.”

Claim Objections

7. Claims 3-11 are objected to because the claim is dependent form a rejected claim.

Conclusion

8. Claims 1 and 19 are rejected, claims 3-11 are objected to; and it appears that claims 17-18 are free of art.

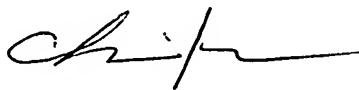
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

April 6, 2007